

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 3

Complete if Known

Application Number	10/575,132
Filing Date	July 7, 2006
First Named Inventor	Sarah Donald
Art Unit	1612
Examiner Name	Chris E. Simmons
Attorney Docket Number	13566.105014

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
/C.S./		WO 03/020259	03-13-2003	Cancer Research Technology Limited		

Examiner
Signature

/Chris Simmons/

Date
Considered

05/17/2009

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Sheet 2 of 3	Attorney Docket Number	13566.105014	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Alexopoulos, "Phase II study of pegylated liposomal doxorubicin (Caelyx(R)) and docetaxel as first-line treatment in metastatic breast cancer," Ann. Oncol., 2004, 15(6):891-5	
		D'Incalci et al., "Unique Features of the Mode of Action of ET-743", The Oncologist, 7, p. 210-216, June 2002	
		Donald et al, "Comparison of four modulators of drug metabolism as protectants against the hepatotoxicity of the novel antitumor drug yondelis (ET-743) in the female rat and in hepatocytes in vitro," Cancer Chemother Pharmacol, April 2004, vol. 53, pp. 305-12	
		European Medicines Agency (EMA), "Scientific Discussion" from the European Public Assessment Report for Yondelis®, Revision 1, published March 31, 2008, downloaded from the internet on April 2, 2008, from the website << http://www.emea.europa.eu/humandocs/Humans/EPAR/yondelis/yondelis.htm >>	
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		Gourley C. et al., "Malignant mixed Mesodermal Tumours - Biology and Clinical Aspects," European Journal of Cancer, 2002, vol. 38, no. 11, pages 1437-1446	
		Halm et al., "A phase II study of pegylated liposomal doxorubicin for treatment of advanced hepatocellular carcinoma," Ann. Oncol., 2000, 11(1):113-114	
		Hoekman et al., "A phase I/II study of dose-escalated docetaxel given two weekly in combination with a fixed dose of G-CSF," European Journal of Cancer, vol. 37, page S76, Abstract 270, October 22, 2001	

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		Horstmann et al., "Risks and Benefits of Phase I Oncology Trials, 1991 through 2002," New England Journal of Medicine, vol. 352, pages 895-904; March 3, 2005	
		Lau et al., "A Phase I and Pharmacokinetic Study of Ecteinascidin-743 (Yondelis) in Children with Refractory Solid Tumors." Clinical Cancer Research, vol. 11, pp. 672-677, Jan. 15, 2005	
		PR Newswire, PR Newswire, October 14, 2001, 4 pages	
		Puchalski et al., "Pharmacokinetics of Ecteinascidin 743 Administered as a 24-h Continuous Intravenous Infusion to Adult Patients with Soft Tissue Sarcomas associations with Clinical Characteristics, Pathophysiological Variables and Toxicity," Cancer Chemotherapy and Pharmacology, 2002, vol. 50, no. 4, pages 309-319	
		Reo-Listo 2002 "Doxorubicin," entries 86-056 through 86-062, 2002 not in English	
		Sarosy et al., "Phase I Study of $\alpha 2$ -interferon plus Doxorubicin in Patients with Solid Tumors," Cancer Research, vol. 46, pp. 5368-5371, 1986	
		Schwartzmann G. et al., "Marine Organisms as a Source of New Anticancer Agents," The Lancet Oncology, 2001, vol. 2, no. 4, pages 221-225	
		Twelves et al., "Phase I and pharmacokinetic study of Yondelis TM (Ecteinascidin-743; ET-743) administered as an infusion over 1 h or 3 h every 21 days in patients with solid tumours," European Journal of Cancer, vol. 39, p. 1842-1851, 2003; available online August 14, 2003	
		Wollina, "Multicenter study of pegylated liposomal doxorubicin in patients with cutaneous T-cell lymphoma," Cancer 2003, 1:98(5):993-1001, published online July 24, 2003	

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